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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,717

08/16/2006

Bo-Lennart Johansson

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EXAMINER

SAUNDERS, DAVID A

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,717	Applicant(s) JOHANSSON ET AL.	
	Examiner David A. Saunders	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/16/09 & 5/20/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,8-16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,8-16 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

AMENDMENT ENTRY

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/20/09 has been entered.

The Transmittal sheet filed with request for continued examination on 5/20/09 indicates that a submission is "Enclosed" as an "Amendment/Reply". The "Amendment/Reply" filed on 5/20/09 has presented no listing of the claims. The remarks/arguments provided on 5/20/09 appear to assume that the After Final amendment of 3/16/09 has been entered. It is noted that the Transmittal sheet filed on 5/20/09 did not have a checked box by "Previously submitted..."; however, since the Transmittal sheet states, by this box, that:

If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

Therefore, the previously filed after FINAL amendment of 3/16/09 has been entered. Following entry of the Amendment of 3/16/09, Claims 5, 8-16 and 18 are pending and are under examination.

CORRECTIONS REGARDING PREVIOUS OFFICE ACTION

The following corrections pertain to the previous Office action:

At page 5, line 1, "Claims 1, 17 and 26-39" should have read as –Claims 1, 17 and 26-29--.

At page 6, last para, lines 1-2, "respect to dependent claim 4," is surplusage.

OBJECTION(S)/REJECTION(S) OF RECORD WITHDRAWN

The amendment has overcome previously stated issues as follows:

The rejection of claim(s) 1, 17 and 26-29 under 35 USC 112, 2nd paragraph, since all of these claims have been cancelled.

The rejection of claim(s) 1, 17 and 26-29 under 35 USC 112, 1st paragraph, since all of these claims have been cancelled.

The prior art rejection of claim(s) 1, 17 and 26-29 based upon Lihme et al in view of Prior et al, since all of these claims have been cancelled.

CLARIFICATION REGARDING ADVISORY ACTION

In the remarks filed on 5/20/09 applicant has requested clarification concerning the examiner's position that the after FINAL amendment incorporating the limits of claim 6 into claim 5 (and into claim 18) would not overcome the rejection of record. More particularly, applicant questioned why the examiner stated in the advisory action that "the amendment would not overcome Belew et al in view of Prior et al (i.e., the rejection under 35 U.S.C. 103(a))", since claim 6 had been rejected over Belew et al under 35 U.S.C. 102(b) or (e). It is to be noted that the Advisory action of 4/8/09, in fact, indicated that insertion of the limits of claim 6 into claim 5 "does not overcome the rejection of record based upon Belew et al, (emph. Added) or upon Belew et al in view of Prior."

The examiner thus, in fact, did consider that the amendment would not overcome the rejection of record, based upon Belew et al alone (i.e. the 102 rejection). The reason that the examiner further stated the amendment would not overcome the rejection based upon Belew et al in view of Prior (i.e. the 103 rejection) was because, clearly, if the rejection of base claim 5 would be maintained under 102, then all of the claims depending from claim 5 should remain rejected under 103.

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MAINTAINED MODIFIED REJECTION(S) UNDER 35 USC 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 8-10, 16 and 18 are rejected under 35 USC 102(b) or (e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Belew et al (US 6,852,230 or WO 02/053288).

WO 02/053288 has 102(b) date, as of its publication date of 7/11/02, since it was published more than one year prior to applicant's Swedish priority date of 2//27/04. US 6,852,230 has a 102(e) date of 6/19/03. For convenience the examiner will only refer to US 6,852,230 by col. and line numbers.

Belew et al teach multi-modal affinity ligands containing an aromatic or heteroaromatic ring and a carboxylic acid group, as a weak cation exchange group. Proteins such as BSA or IgG can be adsorbed thereto and then eluted therefrom. See

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the ligands listed in Table I, with the absorbance maximum and recovery percentages indicated. From the structures of the mono- or bicyclic aromatic or hetero aromatic ligands disclosed in Table I, it is noted that numerous of these have structures consistent with the limitations of instant claim 5.

Regarding the second "contacting" step of claim 5, note the teaching that there can be further purification steps, such as "traditional ion-exchange chromatography" (col. 1, line 66-col. 2, line 12 and col. 3, lines 10-27).

Regarding the concluding "wherein" clause of claim 5, note cell cultures taught at col. 13, lines 42+.

Regarding dependent claim 8, the taught carboxylic acid group is a weak cation exchange group.

Regarding dependent claim 16, the exemplified IgG preparations would contain polyclonal antibodies.

From the above noted teachings, instant method claims 5, 8-10 and 16 are considered anticipated on the basis that all aspects of the claims are taught within the four corners of the reference. Alternatively, the claims are considered to have been obvious, should applicant argue that one would have had to select certain of the ligands listed in Table I, in order to have a ligand that has the structural features consistent with the limits of instant claim 5. Also, the claims are considered to have been obvious, should applicant argue that the teachings of Belew et al concerning purification of large molecular weight substances from cell cultures (col. 13, lines 42+) constitute a mere suggestion.

Regarding independent claim 18, note the teachings at col. 7, lines 7+ concerning "stochastic ion-exchangers", which have 2 kinds of ligands("Ligand 1" and "Ligand 2"). Ligand 1 can be one for ion-exchange, while Ligand 2 can be one "that solely acts by hydrophobic interaction and or electron donor-acceptor interaction (col. 7, lines 49-57). Note the types of moieties which provide for hydrophobic interaction and or electron donor-acceptor interaction taught at col. 8, lines 18-31.

Claims 5 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belew et al in view of Prior et al (5,118,796).

The Belew et al reference has been cited supra, against claim 5, for showing a method involving the contacting of antibodies/immunoglobulins with a multi-modal chromatography medium/ matrix/resin, followed by the addition of an eluent to release the antibodies/immunoglobulins therefrom. The eluate is then further purified via a second chromatography step, such as an ion-exchange chromatography step. Prior et al show a similar sequence of steps in method involving the contacting of antibodies/immunoglobulins with a cation chromatography medium/ matrix/resin, followed by the addition of an eluent to release the antibodies/immunoglobulins therefrom. The eluate is then further purified via a second chromatography step, which is an anion-exchange chromatography step. Since the sequences of steps taught by both Belew et al and Prior et al are similar, it would have been obvious that the second chromatography step of Belew et al would be conducted with an anion exchange resin. Thus instant dependent claim 11 would have been obvious.

Regarding claim 12, there is no reason why a second ion exchange medium, which is an anion exchange medium, could not a mixed mode anion exchanger, particularly in view of the fact that Belew et al note that mixed-mode cation exchangers were art known (col. 5, lines 12-25).

Regarding dependent claims 13-14, note Fig. 1 of Prior et al. This teaches an embodiment in which the immunoglobulin is adsorbed to and then eluted from the anion exchange column (right most track of Fig. 1) and an embodiment in which the immunoglobulin flows through the anion exchange column (middle track of Fig. 1).

Regarding dependent claim 15, Prior et al show purification of monoclonal antibodies (col. 9, lines 10+).

RESPONSE TO APPLICANT'S ARGUMENTS

Applicant's arguments filed 3/16/09 have been fully considered but they are not persuasive for the following reasons.

With respect to the 102 rejection over Belew et al, applicant has argued that Belew et al merely show mixed modal cation exchange of BSA or of IgG as “a model protein” in a method of desalting. Applicant has further argued that the reference does not show that the taught resins can be used as a first chromatography resin for antibody purification from a cell culture liquid or fermentation broth. However, it has been noted supra that Belew et al clearly direct one to use the taught resins with liquids of high ionic strength, such as “fermentation broths/liquids, for instance from the culturing of cells and liquids derived therefrom” (col. 13, lines 42-45).

The attorney has also argued that fermentation broths and cell culture fluids are too complex for use with the resins of Belew et al because such liquids contain host cell proteins, nucleic acids etc.” This is a mere attorney conclusion and has been stated without any factual reasons as to why one of skill would have considered the resins of Belew et al to be unusable with such fermentation broths and cell culture fluids. The Office finds that the inventive entity of the cited Belew et al patent, has certain inventors in common with those of the instant inventive entity. The Office therefore finds it self-serving for applicant to argue that fermentation broths and cell culture fluids are too complex for use with the resins of Belew et al, since one or more individuals of the instant inventive entity taught that fermentation broths and cell culture fluids could be used with the resins of Belew et al.

Applicant’s arguments filed on 3/16/09 have only argued the 102 rejection over Belew et al and have not specifically argued the 103 rejection over Belew et al in view of Prior et al. Since the Office has maintained the rejection over Belew et al alone, the rejection over Belew et al in view of Prior et al has been maintained.

CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays. The examiner's supervisor, Ram Shukla, can be reached

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on 571-272-0735. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 7/20/09 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644